



Attachment B – Specifications
RFx No. 3000006448 Title: Pipette Calibration Services –
LDH – Office of Public Health

To establish a contract for pipette calibrations including complete preventative maintenance, 24-hour pipette service on pre-scheduled calibrations, for LDH – Office of Public Health for the period of date of award through June 30, 2017.

*Pricing on all lines must be complete including shipping, handling, calibration, and complete preventative maintenance service. Do not add separate prices for shipping or handling. OEM Parts are not covered under this contract. If parts are needed, a separate quote for parts must be given to the agency and the agency with either issue a separate PO for the parts or pay with their credit card.

Pipet Calibration and Preventative Maintenance Services following ISO 8655 criteria for pipets listed in Appendix A

ISO 8655:2002, was written specifically to define the requirements necessary to produce accurate and reliable calibrations of piston pipettes and other closely-related measurement equipment. It details the required methods, test conditions, test equipment, reporting requirements and includes requirements for reporting the required measurement uncertainty values. Today, it is the most critical ISO standard for calibrating piston-operated pipettes, burettes, diluters, and dispensers.

Adherence to the ISO 8655 standard covers air displacement pipettes and positive displacement pipettes, single channel and multichannel pipettes (both fixed and adjustable volume) as well as both manual pipettes and automated pipettes, often called motorized pipettes or electronic pipettes.

The ISO 8655 standard precisely defines 6 elements required for accurate, repeatable, ISO-compliant measurements:

Acceptable Measurement Uncertainties

Measurement uncertainty is defined as a quantitative value representing a calculated level of ‘doubt’ or potential measurement error occurring from external influences, and based on the quality, standards and controls maintained or omitted from a calibration event. ISO accredited laboratories are required to verify, calculate and report measurement uncertainty for every calibration.

Maximum Permissible Errors

Maximum Error Limits for piston-operated pipettes are clearly defined in ISO 8655. The standard characterizes both the maximum permissible systematic error, as well as the maximum permissible random error limits for a device at specific volumes ranging from 1-10,000uL. These errors are doubled for multichannel pipettes. Most pipette manufacturer's tolerance specifications fall well below these limits, but at low volume measurements, meeting ISO 8655 tolerances can be a challenge for many service providers.

Maximum permissible errors for Air Displacement and Certain Positive Displacement pipettes – [Reference: ISO8655-2:2002, pg. 6]



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Nominal volume μl	Maximum permissible systematic error		Maximum permissible random error	
	$\pm \%$	$\pm \mu\text{l}^a$	$\pm \%^b$	$\pm \mu\text{l}^c$
1	5,0	0,05	5,0	0,05
2	4,0	0,08	2,0	0,04
5	2,5	0,125	1,5	0,075
10	1,2	0,12	0,8	0,08
20	1,0	0,2	0,5	0,1
50	1,0	0,5	0,4	0,2
100	0,8	0,8	0,3 ^d	0,3 ^d
200	0,8	1,6	0,3 ^d	0,6 ^d
500	0,8	4,0	0,3	1,5
1 000	0,8	8,0	0,3	3,0
2 000	0,8	16	0,3	6,0
5 000	0,8	40	0,3	15,0
10 000	0,6	60	0,3	30,0

Methodology

ISO 8655 states that the primary methodology for measurement of piston-operated pipettes and related measurement apparatus is through gravimetric measurement analysis. Included are the minimum balance requirements at each test volume, important for reporting measurement accuracy at the appropriate resolution. For example, you wouldn't weigh yourself on a truck scale. Pipette measurements face the same challenge for many providers. This standard also requires control (not just monitoring) of test conditions, along with minimum data points for a valid representation of device performance and measurement analysis.

Minimum Balance Requirements – [Reference: ISO8655-6:2002, pg. 2]

Selected volume ^a of apparatus under test V	Resolution mg	Repeatability and linearity mg	Standard uncertainty of measurement mg
$1 \mu\text{l} \leq V \leq 10 \mu\text{l}$	0,001	0,002	0,002
$10 \mu\text{l} < V \leq 100 \mu\text{l}$	0,01	0,02	0,02
$100 \mu\text{l} < V \leq 1\,000 \mu\text{l}$	0,1	0,2	0,2
$1 \text{ ml} < V \leq 10 \text{ ml}$	0,1	0,2	0,2
$10 \text{ ml} < V \leq 200 \text{ ml}$	1	2	2

Lab and Environmental Conditions

To be considered valid by ISO 8655, pipette measurements must occur in a strictly controlled, vibration-free test environment. The acceptable ranges of environmental conditions are defined as:

- Temperature – constant [$\pm 0.5^\circ\text{C}$], 15-30°C



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- Relative Humidity – >50%
- Air Flow – draft free
- Static - ~0
- Evaporation Rate - ~0
- Vibration - ~0
- Altitude - Ground Level

Process Requirements

The ISO 8655 standard defines a step-wise procedure for generating valid, reliable measurement data. Procedures include proper technique for tip installation, pre-wetting, aspiration and dispensing technique, measurement container requirements, required number of measurements, evaporation rate determination and time lapse for test completion.

Pipet Calibration and Preventative Maintenance Services - Includes Laboratories calibration certificate, 4 ‘As Found’ data points, 10 ‘As Left’ data points, and a pipette calibration service label for pipets listed in Appendix B

Contract Notes:

24 hour turnaround or same day service acceptable

Off-site shipping to ISO 8655 accredited calibration site.

As to comply with regulations, upon request, OPH Laboratory will provided tips commonly used with specific pipettes.

Pipet calibration to include the following preventative maintenance services:

- fully disassemble each pipette
- Perform a thorough evaluation of functionality
- Clean and polish pistons
- Replace piston lubricants
- Change piston o-rings and seals
- Assess the integrity of and replace any worn or damaged parts
- Remove contaminating residues from inner and outer components
- Make any necessary repairs, as approved



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- Reassemble and verify functionality ahead of calibration
 - Perform a formal leak test procedure to confirm functionality and performance

For pipettes that fail calibration, OPH Laboratory must be notified within 24 hours and if repair and recalibration is needed, a quote must be sent to Danielle.haydel@la.gov for approval prior to continuation. Remaining pipets in the same shipment that pass calibration should be shipped as completed and not held with the failed pipettes. Reports on pipettes that failed calibration need to include 'As Found' data as well as 'As Left' data. Pipettes that continue to fail after recalibration must be clearly identified.

Assume a quantity of 10 shipments between the Date of Award thru June 30, 2017.

Passed pipettes must be returned with individual calibration certificates reflecting the testing results and an indication of pass or fail. Calibration stickers must be adhered to each pipet indicating calibration date and calibration due date based on if the pipet is indicated as needing an Annual or BiAnnual calibration.